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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/439,313	11/12/99	DILLON	D 210121.427C9

EXAMINER	
LUNDGREN, J	
ART UNIT	**PAPER NUMBER**
1631	8

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DATE MAILED: 03/28/01

03/28/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	09/439,313	DILLON ET AL.	
	Examiner	Art Unit	
	Jeffrey Lundgren	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-64* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15)☐ Notice of References Cited (PTO-892)
16)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18)☐ Interview Summary (PTO-413) Paper No(s). _____ .
19)☐ Notice of Informal Patent Application (PTO-152)
20)☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3, 14-17, and 64, are drawn to isolated polypeptides and recombinant proteins, classified in class 530, subclass 300.

II. Claims 4-10, 60-61, and 63, are drawn to isolated polynucleotides, expression vectors comprising said polynucleotides, and host cells transformed with said expression vectors, classified in class 435, subclass 69.1.

III. Claims 11-13, are drawn to antibodies, classified in class 424, subclass 130.1.

IV. Claims 14-17, are drawn to fusion proteins, classified in class 530, subclass 402.

V. Claim 18, is drawn to an isolated polynucleotide encoding a fusion protein, classified in class 536, subclass 23.4.

VI. Claim 19, 23, and 33, are drawn to a pharmaceutical composition, and method for the use thereof, classified in class 424, subclass 439.

VII. Claims 20-22, 24, and 33, are drawn to vaccines, and method for the use thereof, classified in class 424, subclass 184.1.

VIII. Claims 25-26, are drawn to a pharmaceutical composition, classified in class 424, subclass 192.1.

IX. Claims 27-30, are drawn to a vaccine composition, classified in class 424, subclass 183.1.

X. Claims 31-33, are drawn to a method for inhibiting the development of a cancer in a patient using an antigen presenting cell, classified in class 424, subclass 93.1.

XI. Claims 34-35, are drawn to a method for removing tumor cells from a biological sample, classified in class 424, subclass 810.

XII. Claims 36, 50-52, are drawn to a method for inhibiting the development of a cancer in a patient using an oligonucleotide, classified in class 514, subclass 44.

XIII. Claims 37-39, are drawn to a method for stimulating and/or expanding T cells for a prostate-specific protein, classified in class 424, subclass 154.1.

XIV. Claims 40-41, are drawn to a method for inhibiting cancer in a patient comprising incubating CD4+ and/or CD8+ T cells, classified in class 435, subclass 343.2

XV. Claims 42-49, and 56-59, are drawn to a method for detecting the presence of cancer and monitoring its progression using polypeptides, classified in class 435, subclass 7.1.

XVI. Claims 53-55, and 62, are drawn to a method for monitoring the progression of cancer using oligonucleotides, classified in class 435, subclass 6.

2. The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different products/apparatus, restriction is deemed to be proper because these products appear to constitute patentably distinct inventions for the following reasons: Groups I-IX are directed to products that are functionally different, and are not required one for the other. Therefore, a search and examination of all the products in one patent application would result in an undue burden, since the searches for the products are not co-extensive, the classification is different, and the subject matter is divergent.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods/processes, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Groups X-XVI are directed to methods that are functionally different, and are not required one for the other. Therefore, a search and examination of all the methods in one patent application

would result in an undue burden, since the searches for the methods are not co-extensive, the classification is different, and the subject matter is divergent.

Inventions I and III-V, and Inventions X, XI, and XIII-XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptides of Groups I and II-V can be used with any of the methods of X, XI, and XIII-XV.

Inventions II, and Inventions XII and XVI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acids of Group II can be used with any of the methods of X, XI, and XIII-XV.

Inventions VI-IX, and Inventions X-XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the vaccines and/or pharmaceutical compositions of Group VI-IX can be used with any of the methods of Groups X-XIV.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, and the serious burden that would be imposed on the Office to search more than a single invention, restriction for examination purposes as indicated is proper.

Sequence Election Requirement

In addition, Groups I-XVI detailed above read on patentably distinct complex sequences. The sequence are patentably distinct because each sequence is chemically and functionally different, and a further restriction is applied to each Group. For the elected Group, Applicants must further elect a single sequence.

Examination will be restricted to only the elected sequence. Applicants are informed that the restriction requirement for electing a single sequence, is *not* a species election.

4. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Sequence Rules

5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements for Patent Applications Containing Nucleotide Sequence and/or Amino Acid Sequence Disclosures.

A CRF, fully compliant with the above stated rules, is **required** for any search and examination to proceed. A fully responsive communication will contain both a proper election of a group, as well as fulfillment of the sequence rules, as required.

Inquiries

6. Any inquiries concerning the *merits* of this communication or earlier communications from the Examiner should be directed to Jeffrey S. Lundgren, whose

telephone number is (703) 306-3221. The Examiner can normally be reached on Monday-Friday from 7:00 AM to 5:00 PM (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Michael Woodward, can be reached at (703) 308-4426.

Any inquiries of a *general* nature relating to this application should be directed to Ms. Pauline Farrier, Patent Analyst for Art Unit 1631, whose telephone number is (703) 305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Group 1631 using (703) 308-0294. Please notify the Examiner of incoming facsimiles prior to sending papers to the aforementioned fax number. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

Jeffrey S. Lundgren, Ph.D.

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER

Application No.: 09/439,313

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- [X] 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- [X] 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- [X] 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- [ ] 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- [ ] 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- [ ] 6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- [ ] 7. Other: _____

Applicant Must Provide:

- [X] An initial or substitute computer readable form (CRF) copy of the "Sequence Listing".
- [X] An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- [X] A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216
For CRF Submission Help, call (703) 308-4212
PatentIn Software Program Support
Technical Assistance.....703-287-0200
To Purchase PatentIn Software.....703-306-2600

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